

**REMARKS**

In response to the Official Action mailed November 24, 2006, Applicants submit the following amendments and remarks. The Applicants regretfully note that in response to the Office Action dated 8/11/2006 filed along with the Request for Continued Examination, the original claims 1-33 were included in the response by mistake. The Applicants did not intend to amend claims in the response to Office Action dated 8/11/2006. The present response reinstates the claims 1-33 as they stood after amendment in response to Office Action dated 2/16/2006. These claims were deemed to have overcome the rejection under 35 U.S.C. § 112 and 35 U.S.C. § 102 that have been reinstated in the present Office Action(dated 11/24/2006). The arguments relating to the rejection under 35 U.S.C. § 112 and 35 U.S.C. § 102 that were made previously and accepted by the Examiner have been repeated below for sake of completeness.

**REJECTION - 35 U.S.C. §112**

Claim 8 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which Applicant regards as the invention. Specifically, the Examiner asserts that the limitation, "said fingers" in line 2 of claim 8 lacks an antecedent basis. In response to this objection, Applicants have amended claim 8 so as to depend from claim 3, thereby providing the correct antecedent basis for the phrase "said fingers".

**REJECTION - 35 U.S.C. §102 - *SCHLUZAS***

Claims 25, 26 and 30-33 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Publication

2002/0143328 to *Schluzas, et al.* In response to this rejection, Applicant has amended claims 25 and 30 to include a recitation directed towards a positioning means and a positioner, respectively. The positioning means and/or positioner is moveable with respect to a bone fastener and also allows for the bone plate to be positioned at different locations, *i.e.*, heights, relative to a vertebral body. This is because, as the bone fastener is positioned within the bone, the positioner or positioning means may be moved upwards or downwards along the bone fastener such that the spatial relationship of the bone plate and vertebral body may be adjusted as required. The positioner and positioning means may be moved with respect to the bone fastener, that requiring the bone fastener to be further embedded in the vertebral body or slightly removed from the vertebral body. But the bone plate may still be adjusted relative to the vertebral body.

In contrast, *Schluzas* discloses an intermediate portion 32 on a fastener 16, which has wrenching flats 34. The intermediate portion 32 is integrally formed with the fastener and may not be moved along the fastener, thereby limiting the position of the bone plate relative to the fastener. This would require the fastener to be adjusted in order to adjust the height of the bone plate above a vertebrae, once the fastener has been positioned within the vertebrae. In contrast to the present invention, which simply allows the positioner or positioning means to be adjusted while the bone fastener remains in the same position relative to the vertebral body. Thus, Applicant asserts that newly amended independent claims 25 and 30 as well as their dependent claims are in condition for allowance over the art cited.

**REJECTION - 35 U.S.C. §102(b) - LIN**

Claims 1-13, 16-18 and 25-27 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Nos. 5,613,968 to *Lin*. Similar to *Schluzas*, *Lin* discloses a protruding edge 321 that is integrally formed on a double threaded screw 300. The protruding edge 321 similar to the intermediate portion of *Schluzas* may not be maneuvered relative to the bone fastener and rather is fixed to the bone fastener. This limits *Lin* in that the height of bone plate, or in this case, a rod, relative to a vertebral body may not be adjusted without removing the bone fastener from the vertebrae or further inserting the bone fastener into the vertebral body. Thus, for arguments consistent with those made with regard to *Schluzas*, Applicant asserts that newly amended claim 1 as well as claim 25 and their respective dependent claims are in condition for allowance over the art cited.

**REJECTION - 35 U.S.C. §103- SCHLUZAS**

Claims 1-33 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication 2002/0143328 to *Shluzas et al.* This reference was cited in the previous Official Action. The Examiner cites *Shluzas* and asserts that it discloses most of the elements of the claims for which it is cited against, however, the Examiner acknowledges that it does not disclose a stopping element separable and adjustable as included within the claims of the present application. The Examiner asserts that it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the stopping element (240) separate from the shaft of the bone screw. Applicants respectfully traverse this rejection.

To make a claim obvious, a reference must teach, disclose or suggest all elements of a claim. *Shluzas et al.*

does not teach, disclose or suggest all elements of claim 1 for the reasons discussed hereafter.

First, the Applicants respectfully note that making stopping element (240) separate from the shaft, as suggested by the Examiner, is not sufficient to obtain the invention of claim 1. In addition to making the stopping element (240) separate, one will have to provide internal threads to this separate part and on top of that one will have to extend the threads on end portion (26) to allow the now separated stopping element to be threaded on to the end portion and thereby "be located at different positions along said bone fastener" as recited in claim 1. Thus, Examiner's contention that it would be obvious to make stopping element separate, even if correct, would not lead to the construct of claim 1.

Second, the Examiner relies on *Nerwin* for the proposition that "constructing a formerly integral structure in various elements involves only routine skill in the art." The Applicants disagree. *Nerwin* stands for the proposition that "[t]he mere fact that a given structure is integrated does not preclude its consisting of various elements." This is different from what the Examiner cites *Nerwin* for and certainly does not mean that an integral structure makes "constructing a formerly integral structure in various elements" obvious. A marked up copy of *Nerwin* highlighting relevant language is attached herewith for your ready reference.

Additionally, the Examiner's reliance on *In re Stevens* is also misplaced. In *In re Stevens* the need for adjustment was long recognized as desirable. In contrast, in *Shluzas* there is absolutely no recognition that adjustability of height of plate (12) is desired. Thus, the Examiner's argument that "[i]t would have been further obvious to one having ordinary skill in the art at the time the invention was made to construct the removable stopping element (240) with internal threads, since it

has been held that the provision of adjustability, where needed, involves only routine skill in the art" is not supported by *In re Stevens* in absence of demonstrated recognition that adjustability of height of plate is desired. A marked up copy of *In re Stevens* highlighting relevant language is attached herewith for your ready reference. For the reasons discussed above *Shluzas et al.* does not teach disclose or suggest all elements of claim 1 and therefore, claim 1 is not obvious over *Shluzas et al.*

Similarly, independent claim 25 of the present application includes a "positioning means" that enables the height of the bone plate relative to a vertebral body to be adjusted without movement of the bone fastener. Independent claim 30 recites a "positioner . . . having an engagement element" that enables the height of the bone plate relative to a vertebral body to be adjusted without movement of the bone fastener. These features are also not disclosed, taught or suggested in *Shulzas* for same reasons as discussed in context of claim 1. Thus, Applicants urge that independent claims 1, 25 and 30 as well as their dependent claims are not obvious over *Shluzas* and should be deemed allowed.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone Applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

Application No.: 10/806,736

Docket No.: SPINE 3.0-423

If there are any additional charges in connection with this requested Amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

By Dixit Mayankkumar  
Mayankkumar Dixit  
Registration No.: 44,064  
LERNER, DAVID, LITTENBERG,  
KRUMHOLZ & MENTLIK, LLP  
600 South Avenue West  
Westfield, New Jersey 07090  
(908) 654-5000  
Attorney for Applicant

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